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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,816	11/09/2006	Barry D. Shur	050508-1390	3894

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EXAMINER	
CARLSON, KAREN C	
ART UNIT	PAPER NUMBER
1656	

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12/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,816	SHUR ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 43-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 43-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 10-42 have been cancelled. Claims 1-9 and 43-52 are currently pending and are under examination.

Benefit of priority is to October 17, 2003.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 and 43-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claims 1 and 9, it is not clear what the activity of the polypeptide is because the term "modulate" can mean to increase or to decrease gamete adhesion.

In Claims 4 and 5, for example, it is not understood how a structure can have two different functions, one to inhibit sperm binding to unfertilized zona pellucida and the other to promote this binding.

In Claim 9, "Nos:" should be – NOs: —.

In Claims 7, 9, 49, and 50, the polypeptide comprises SEQ ID NO: 2-7. SEQ ID NO: 2 comprises each of SEQ ID NOs: 3-7. Thus, it is not clear if the polypeptide must comprise SEQ ID NO: 2 and therefore SEQ ID NO: 3-7 by default, or if the polypeptide must alternatively comprises SEQ ID NO: 2, 3, 4, 5, 6, **OR** 7. Please clarify.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6-9 and 43, and 47–52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In these claims, there is no correlation of structure with function. See pages 49-52 of the specification in which the activity of SED1 is postulated. Therefore the claims lack written description.

Factors to be considered for written description are:

1. level of skill and knowledge in the art is high;

2. partial structure is provided via domains and fragments of sequences but the function to "modulate" gamete adhesion is indefinite.

3. physical and or chemical properties are disclosed but the function to modulate gamete adhesion is indefinite.

4. functional characteristics alone or coupled with a known or disclosed correlation between structure and function is not provided because the claims read on domains and fragments of sequences;

5. method of making the claimed invention is not provided because one skilled in the art does not know what fragment of a sequence will increase or decrease gamete adhesionl.

Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to he conclusion that the applicant was in possession of the claimed species of the invention is sufficient (MPEP 2163).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 and 43-52 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1 004 664 A1; published May 31, 2000.

'644 teaches composition of mouse lactadherin SEQ ID NO: 2, in a liposome, for example – see the Claims. This 426 amino acid sequence differs from instant SEQ ID NO: 2 at G110E, S131Y, T159H, S272L, and A357E. Lactadherin is also knows as Milk Fat Globule – EGF-Factor VIII (MFG-E8) – see page 9, line 44 of '644. MGF-E8 is also known in the art as SED1. Therefore, lactadherin is SED1 and comprises two discoidin/C domains and two EGF domains as set forth in the specification.

Therefore, '644 teaches a pharmaceutical composition comprising a polypeptide comprising at least one discoidin/C domain (**Claim 1**) and at least one EGF domain (**Claim 2**) in a pharmaceutically acceptable carrier such as a liposome (**Claim 3, 43**), wherein the polypeptide comprises SED1 or a fragment thereof (**Claim 6, 47, 48**), wherein the polypeptide comprises fragments of SEQ ID NOs: 2-7 (**Claim 7, 9, 49, 50**).

While '644 does not teach the function of the lactadherin as being in the modulation of gamete adhesion, the discovery of a new function for a known protein does not change the structure of the protein. Thus, **Claims 4, 5, 8, 44, 45, 46, 51, and 52** are included in this rejection because the protein structure is known and therefore the function is inherent to the structure.

Art of Record:

Ceriani et al. (USP 5,972,337, issued October 26, 1999) teach a 46 kD milk fat globular protein having 96.6 % identity to SEQ ID NO: 2. See the sequence alignment attached to the front page of '337, being sent with this Office Action.

Decayre et al. (WO 03/016522, published February 27, 2003) teach composition of mouse lactadherin. This 434 amino acid sequence differs from instant SEQ ID NO: 2 at S131Y, T159H, S263L, and A357E. See the sequence alignment attached to the reference.

Kanai et al. (2000; Identification of a stromal cell type characterized by the secretion of a soluble integrin-binding protein, MFG-E8, in mouse early gonadogenesis. Mechanisms of Development 96: 223-227) teach MFG-E8 having two EGF domains and two discoidin domains.

Stubbs et al. (1990; cDNA cloning of a mouse mammary epithelial cell surface protein reveals the existence of epidermal growth factor-like domains linked to factor VIII-lie sequences. PNAS 87:8417-8421) teach a 51.5 kD protein MFGM having 97.4% identity to SEQ ID NO: 2. See the sequence alignment attached to the reference.

Ogura et al. (1996; Cloning and expression of cDNA for O-acetylation of GD3 ganglioside. Biochem. Biophys Res. Commun. 225: 932-938) teach O-acetyl GD3 having 6 mismatches across SEQ ID NO: 2. See the sequence alignment attached to the reference.

Oshima et al. (Feb., 2002; Secretion of a peripheral membrane protein, MFG-E8, as a complex with membrane vesicles: a possible role in membrane secretion. Eur. J. Biochem. 269: 1209-1218) teach MFG-E8 having two EGF domains and two discoidin domains.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen Cochrane Carlson, PhD

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KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER